SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement ("Agreement") is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General ("OIG-HHS") of the Department of Health and Human Services ("HHS") and TRICARE Management Activity ("TMA") (formerly the Office of Civilian Health and Medical program of the Uniformed Services) [collectively the "United States"]; Steven J. Bander, M.D. ("Bander" or "Relator"); and Gambro Healthcare, Inc. ("Gambro") [hereafter collectively referred to as "the Parties"], through their authorized representatives.

II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

- A. Gambro, a for-profit corporation organized under the laws of the State of Tennessee, is a supplier of renal dialysis services. Gambro, at all relevant times hereto, was in the business of providing renal dialysis and related services to patients with End-Stage Renal Disease ("ESRD"). ESRD is a life threatening condition in which a patient's kidneys are unable to remove toxins from the blood, thus necessitating some form of dialysis treatment. This condition is often suffered by patients who have experienced chronic kidney disease over a period of time.
- B. Gambro Supply Corp., including its predecessor REN Supply
 Corporation (collectively "GSC"), is a sister company to Gambro (i.e. both GSC and
 Gambro are wholly owned subsidiaries of Gambro, Inc., a Colorado corporation). GSC
 was a Durable Medical Equipment Prosthetics Orthotics and Supply company
 ("DMEPOS") in the business of supplying dialysis supplies and equipment to patients

who receive dialysis at home. Home dialysis supplies and equipment may be billed to Medicare either by a dialysis clinic (Method I) or by a DMEPOS company (Method II). A DMEPOS company billing Medicare under Method II may receive higher reimbursement than a dialysis clinic billing Medicare under Method I. Subject to the terms of a plea agreement ("Plea Agreement") between the United States and GSC, GSC shall enter a plea of guilty to an Information charging GSC with a single count of health care fraud, pursuant to 18 U.S.C. § 1347, for factual misrepresentations made by REN Supply Corporation in 1993 and 1996, and not disclosed by GSC until 1998.

- C. Bander is an individual resident of the State of Missouri. On April 13, 2001, the Relator filed a <u>qui tam</u> action in the United States District Court for the Eastern District of Missouri captioned <u>United States of America ex rel Steven J. Bander, M.D. v. Gambro Healthcare U.S., Inc.</u>, which was subsequently amended (hereinafter "the Civil Action"). During the approximate period April 1996 to December 2000, the Relator was a licensed nephrologist who served as Chief Medical Officer for Gambro. As part of his duties, the Relator oversaw medical and nursing services at Gambro's outpatient dialysis centers across the United States.
- D. Gambro, by itself and through its various subsidiaries and related companies, including GSC, submitted or caused to be submitted claims for payment to the Medicare Program ("Medicare"), Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg; to TMA, 10 U.S.C. §§ 1071-1110; and to the Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v.
- E. <u>Covered Conduct</u>. The United States contends it has certain civil claims, as specified in Section III, Paragraph 3 below, against Gambro for engaging in

the following alleged conduct. Unless otherwise specified, the covered period for the conduct alleged below is January 1, 1991 through December 1, 2004 ("Covered Conduct"):

GSC

The United States contends that, from January 1, 1991 to September 30, 2004, GSC existed solely as a billing entity and only for the purpose of maximizing Gambro's Medicare reimbursement for Method II home dialysis supplies and equipment. The United States contends this arrangement violated 42 U.S.C. § 1395rr and 42 C.F.R. § 414.330 because GSC was a shell corporation serving as a billing mechanism for Gambro's dialysis clinics, and thus home dialysis patients were receiving supplies from Gambro, while GSC billed for such supplies at the higher rates reimbursed by Medicare for a DMEPOS company. The United States contends this arrangement also violated 42 C.F.R. § 424.57 because GSC did not meet the requirements to be a DMEPOS company. The United States contends the foregoing resulted in GSC submitting or causing the submission of, false claims to the Medicare, Medicaid, and Tricare Programs (referred to as "government healthcare programs" in Paragraph E) for Method II home dialysis supplies and Gambro submitting, or causing the submission of, false claims to government healthcare programs for support services provided to Method II home patients.

2. The United States contends that, from January 1, 1991 to September 30, 2004, GSC submitted, or caused to be submitted, false claims to government healthcare programs seeking reimbursement for a greater quantity

of supplies, including emergency supplies, than GSC delivered or caused to be delivered to beneficiaries.

Ancillary Drugs and Tests

- assigned diagnosis codes from the standardized International Classification of Diseases, Ninth and/or Tenth Revisions ("ICD-9 codes") when submitting claims to government healthcare programs. Gambro's computer system assigned an ICD-9 code by reference to local medical review policies published by Medicare fiscal intermediaries rather than by reference to patients' actual diagnoses. As a result, the preemptive ICD-9 codes permitted reimbursement for claims for certain ancillary medications and tests that were ordered, prescribed, or administered despite a lack of medical necessity. The United States also contends Gambro administered certain ancillary medications and tests that lacked medical necessity for reasons other than preemptive coding and/or lacked the documentation to support medical necessity, as described below:
 - a. Carnitor The United States contends Gambro, from January 1, 1991 to December 1, 2004, submitted, or caused to be submitted, false claims for Carnitor to government healthcare programs. The United States contends such Carnitor claims were false because they contained preemptive ICD-9 codes, lacked medical necessity, and/or lacked the documentation to support medical necessity;
 - b. Vitamin D The United States contends Gambro, from January 1, 1991 to December 1, 2004, submitted, or caused to be

submitted, false claims to government healthcare programs for Vitamin D drugs. The United States contends such Vitamin D claims were false because they contained preemptive ICD-9 codes, lacked medical necessity, and/or lacked the documentation to support medical necessity;

- c. Iron The United States contends Gambro, from

 January 1, 1991 to December 1, 2004, submitted, or caused to be

 submitted, false claims to government healthcare programs for Iron drugs.

 The United States contends such Iron claims were false because they

 contained preemptive ICD-9 codes, lacked medical necessity, and/or

 lacked the documentation to support medical necessity;
- d. Epogen The United States contends Gambro, from January 1, 1991 to December 1, 2004, submitted, or caused to be submitted, false claims to government healthcare programs for Epogen ("EPO"). The United States contends such EPO claims were false because Gambro administered EPO to patients in higher doses than was medically necessary. The United States contends Gambro, through the administration of more EPO than was medically necessary, maintained patients' hematocrit readings at higher levels, which required additional documentation supporting medical necessity for continuing the administration of EPO. The United States also contends Gambro submitted EPO claims that lacked medical necessity and/or lacked the documentation to support medical necessity;

- e. Electrocardiograms The United States contends
 Gambro, from January 1, 1991 to December 31, 2002, submitted, or
 caused to be submitted, false claims to government healthcare programs
 for routine Electrocardiograms ("EKGs"). The United States contends
 such EKG claims were false because they lacked medical necessity
 and/or lacked the documentation to support medical necessity;

 f. Nerve Conduction Studies The United States
 contends Gambro, from January 1, 1991 to December 31, 2000,
 submitted, or caused to be submitted, false claims to government
- contends Gambro, from January 1, 1991 to December 31, 2000, submitted, or caused to be submitted, false claims to government healthcare programs for routine Nerve Conduction studies. The United States contends such Nerve Conduction claims were false because they lacked medical necessity and/or lacked the documentation to support medical necessity; and
- g. Bone Density Studies The United States contends
 Gambro, from January 1, 1991 to December 31, 1998, submitted, or
 caused to be submitted, false claims to government healthcare programs
 for routine Bone Density studies. The United States contends such Bone
 Density claims were false because they lacked medical necessity and/or
 lacked the documentation to support medical necessity.

Physician Remuneration

4. The United States contends Gambro submitted, or caused to be submitted, false claims to government healthcare programs for services referred, ordered, or arranged for by physicians, physician practices, physician

groups, universities, and hospitals (collectively referred to as "Physicians" in this Paragraph 4 only), which were rendered to patients at dialysis clinics owned and/or operated by Gambro. The United States contends:

- a. Gambro knowingly and willfully offered to pay and/or paid to Physicians illegal remuneration in the form of fees for services as medical directors and/or regional medical directors at the aforementioned dialysis clinics, payments associated with the acquisition of clinics from Physicians, and payments associated with clinic development agreements;
- b. That the illegal remuneration paid by Gambro, described above in Paragraph 4.a., to Physicians was intended to induce such Physicians to refer their patients to the aforementioned dialysis clinics owned and/or operated by Gambro;
- c. That such claims were false because (1) Gambro forfeited its right to bill the government healthcare programs for such services by paying remuneration intended to induce those and other referrals in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and (2) Gambro was required to and did certify on cost reports submitted to fiscal intermediaries that services identified or summarized in each cost report were not provided or procured through the payment directly or indirectly of a kickback or billed in violation of federal law; and

d. That Gambro submitted such claims despite and notwithstanding its knowledge that the claims were false as described above;

Joint Ventures

- 5. The United States contends that Gambro submitted, or caused to be submitted, false claims to government healthcare programs for services referred, ordered, or arranged for by physicians, physician practices, and/or physician groups (collectively, "JV Partners" in this Paragraph 5 only), which were rendered to patients at dialysis clinics owned and/or operated by joint ventures ("JVs") in which Gambro and the JV Partners had ownership interests. The United States contends:
 - a. Gambro knowingly and willfully offered to pay and/or paid to its JV Partners illegal remuneration in connection with the JVs in the form of distributions of income from the JVs, reduction or elimination of losses incurred by the JVs, and the accumulation of equity interest in the JVs;
 - b. That the illegal remuneration paid by Gambro, described above in Paragraph 5.a., was intended to induce the JV Partners to refer their ESRD patients to dialysis clinics owned by the JVs in which Gambro had a significant financial interest;
 - c. That such claims were false because (1) the JVs forfeited their right-to bill the government healthcare programs for such

services by paying remuneration intended to induce those and other referrals in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and (2) the JVs were required to and did certify on cost reports submitted to fiscal intermediaries that services identified or summarized in each cost report were not provided or procured through the payment directly or indirectly of a kickback or billed in violation of federal law; and

- d. That Gambro submitted such claims despite and notwithstanding its knowledge that the claims were false as described above.
- F. The United States also contends that it has certain administrative claims, as specified in Section III, Paragraphs 4 and 5 below, against Gambro for engaging in the Covered Conduct.
- G. Except as to any admissions GSC makes in connection with the Plea Agreement, Gambro denies the allegations of the United States and/or the Relator as set forth above and in the Civil Action, and therefore, this Agreement is neither an admission of liability or wrongdoing by Gambro, nor a concession by the United States or the Relator that its claims are not well founded.
- H. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, the Parties reach a full and final settlement pursuant to the Terms and Conditions below.

III. TERMS AND CONDITIONS

- Gambro agrees to pay and/or allocate the total sum of \$323,630,672.00, plus accrued interest, as specified below:
 - a. Gambro agrees to pay the United States the sum of \$308,390,672.00, plus accrued interest (the "Settlement Amount"), by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney's Office for the Eastern District of Missouri. Gambro agrees to make this electronic funds transfer no later than the Effective Date of this Agreement. Interest shall accrue at the simple rate of 4.125% per annum from the date of October 1, 2004 until the date such funds are paid to the United States;
 - b. Gambro agrees to allocate the sum of \$15,000,000.00 for the purpose of resolving liability, if any, to states for Covered Conduct, pursuant to a preliminary understanding between Gambro and representatives for the states. While not anticipated, to the extent Gambro reaches a settlement with the states for Covered Conduct in an amount less than \$15,000,000.00, then Gambro shall calculate the remaining sum (i.e. the remaining sum shall be \$15,000,000.00 minus the total settlement amount paid to the states) and pay half of such remaining sum to the United States. The other half of the remaining sum shall then be re-allocated to Gambro. In the event Gambro has not entered into a settlement agreement with the states for Covered Conduct within 12 months of the Effective Date of this Agreement, then the \$15,000,000.00 allocation provided for herein shall no longer be effective; and

- c. Gambro agrees to pay Relator and his counsel \$240,000.00 for expenses, attorney's fees and costs, no later than the third business day after the Effective Date of this Agreement. Such amount shall be jointly payable to Relator and all of his counsel.
- 2. Notwithstanding any other provision in this Agreement, if GSC's Plea Agreement is not accepted by the Court or the Court does not impose the agreed upon sentence for whatever reason, this Agreement shall be null and void at the option of either the United States or Gambro. If either the United States or Gambro exercises this option, which option shall be exercised by notifying all Parties, through counsel, in writing within 10 business days of the Court's decision, the Parties will not object and this Agreement will be rescinded. In the event this Agreement is rendered null and void pursuant to the terms of this Paragraph 2, then the period of time between the Effective Date of this Agreement and the date that written notice is provided to all Parties of the exercise of this option, shall not be included for the purpose of determining the applicability of any Parties' defense or other invocation of a statute of limitations, or the doctrine of laches, estoppel, or similar theories.
- 3. Subject to the exceptions in Paragraph 6 below, in consideration of the obligations of Gambro in this Agreement, conditioned upon Gambro's full payment of the Settlement Amount, and subject to Paragraph 19 below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment under this Agreement), the United States, on behalf of itself, its officers, agents, agencies, and departments, agrees to release Gambro, together with its current and former parents, brother and sister corporations, indirect, direct, wholly-owned, and

partially-owned subsidiaries, including any joint ventures involving the operation of dialysis clinic(s) in which Gambro or its subsidiaries have or had an ownership interest, and their predecessors, successors, and assigns ("Gambro Released Entities"), and their current employees, officers and directors, from any civil or administrative monetary claim the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; any statutory provision applicable to the federally-funded programs in this Agreement for which the U.S. Department of Justice has the authority to assert and compromise pursuant to 28 C.F.R. Part 0, Subpart I, section 0.45(d); or the common law theories of fraud, misrepresentation, unjust enrichment, payment by mistake, restitution, recoupment, and disgorgement. The United States further agrees the Settlement Amount includes the United States' share of any monies Gambro may pay to any state and/or any Medicaid program for any overpayment, penalty, or any other monetary recovery related to Covered Conduct, and the Settlement Amount fully discharges and satisfies the United States' claim to any share of any settlement or judgment involving Gambro and any state related to the Covered Conduct.

4. In consideration of the obligations of Gambro in this Agreement and the Corporate Integrity Agreement ("CIA"), which is attached hereto as Exhibit A and is incorporated herein by reference as if fully set forth, conditioned upon Gambro's full payment of the Settlement Amount, and subject to Paragraph 19 (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment under this Agreement), the OIG-HHS agrees to release and

refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Gambro, together with its indirect, direct, whollyowned, and partially-owned subsidiaries and joint ventures that provide outpatient dialysis services, including any holding companies owned by Gambro that in turn own the clinics providing outpatient dialysis services, and their predecessors and successors, under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in Paragraph 6, and Paragraph 10 (regarding GSC), and as reserved in this Paragraph 4. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Gambro, together with its indirect, direct, wholly-owned, and partially-owned subsidiaries and joint ventures that provide outpatient dialysis services, including any holding companies owned by Gambro that in turn own the clinics providing outpatient dialysis services, and their predecessors and successors, from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a)(mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph 4 precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 6, below. In consideration of the obligations of Gambro set forth in this

5. In consideration of the obligations of Gambro set forth in this
Agreement, conditioned upon Gambro's full payment of the Settlement Amount, and
subject to Paragraph 19 below (concerning bankruptcy proceedings commenced within
91 days of the Effective Date of this Agreement or any payment under this Agreement),

TMA agrees to release and refrain from instituting, directing, or maintaining any
administrative action seeking exclusion from the TRICARE Program against the
Gambro Released Entities under 32 C.F.R. § 199.9 for the Covered Conduct, except a
reserved in Paragraph 10 below (regarding GSC), and as reserved in this Paragraph 5
TMA expressly reserves authority to exclude the Gambro Released Entities from the
TRICARE Program under 32 C.F.R. §§ 199.9 (f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii),
based upon the Covered Conduct. Nothing in this Paragraph precludes TMA or the
TRICARE Program from taking action against entities or persons, or for conduct and
practices, for which civil claims have been reserved in Paragraph 6 below.
6. Notwithstanding any term of this Agreement, specifically reserved
and excluded from the scope and terms of this Agreement as to any entity or person

- (including Gambro and Relator) are the following claims of the United States:
 - a. Any civil, criminal, or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);
 - Any criminal liability, subject to the terms of the Plea Agreement between the United States and GSC, which is being entered into contemporaneously with this Agreement;
 - Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;
 - Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

- e. Any liability based upon such obligations as are created by this Agreement;
- f. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- g. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;
- h. Any liability for failure to deliver goods or services due, except as otherwise described in Covered Conduct in Section II, Paragraphs E.2. and E.3.
- i. Any civil or administrative liability of individuals (including current or former directors, officers, employees or agents of the Gambro Released Entities) who, related to the Covered Conduct, are indicted, charged, or convicted, or who enter into a plea agreement. However, as of the Effective Date of this Agreement, if such individuals are legally entitled to repayment from any of the Gambro Released Entities by a claim for indemnification, contribution, reimbursement, or otherwise as a result of a claim brought by the United States, but only to the extent that such individuals' claims are not subject to insurance coverage or payments by third parties, the release provided in Paragraph 3 above shall also apply to such individuals with respect to that claim.
- 7. The Relator agrees this settlement is fair, adequate, and reasonable under all circumstances, and will not challenge this Agreement pursuant to 31 U.S.C. § 3730(c)(2)(B), and expressly waives the opportunity for a hearing on any such

objection. Payment by the United States of an award to the Relator, as provided for b
31 U.S.C. § 3730(d)(1), is not included in this Agreement, but will be the subject of a
separate agreement between the United States and the Relator. If the United States
and the Relator are unable to reach an agreement regarding the Relator's share
pursuant to 31 U.S.C. § 3730(d)(1), any such disagreement will be resolved by
proceedings in the United States District Court for the Eastern District of Missouri.
8. In consideration of the obligations of Gambro in this Agreement,
conditioned upon Gambro's full payment of the sums provided for in Section III,
Paragraphs 1.a. and 1.c., the Relator, for himself, and for his heirs, successors,

- conditioned upon Gambro's full payment of the sums provided for in Section III,
 Paragraphs 1.a. and 1.c., the Relator, for himself, and for his heirs, successors,
 attorneys, agents, and assigns, fully and finally releases, waives, and forever
 discharges the Gambro Released Entities, and any current or former employees,
 officers, directors, and agents of the Gambro Released Entities, from any claims the
 Relator has asserted, could have asserted, or may assert in the future relating in any
 way to the Covered Conduct and/or the Civil Action, including but not limited to any
 claims arising under the False Claims Act, 31 U.S.C. §§ 3729-3733.
- 9. Gambro has entered into a CIA with OIG-HHS, attached as Exhibit A. Gambro shall implement its obligations under the CIA as set forth therein.
- 10. In compromise and settlement of the rights of OIG-HHS to exclude GSC pursuant to 42 U.S.C. § 1320a-7(b)(7), and if a guilty plea is entered to the criminal charge described in Section II Paragraph B, under 42 U.S.C. § 1320a-7(a)(1), GSC shall be permanently excluded under this statutory provision from Medicare, Medicaid, and all other Federal health care programs, as defined in 42 U.S.C. § 1320a-7b(f). Such exclusion shall have national effect and shall also apply to all other

Federal procurement and nonprocurement programs. Federal health care programs shall not pay anyone for items or services, including administrative and management services, furnished, ordered, or prescribed by GSC in any capacity while GSC is excluded. This payment prohibition, described above, applies to GSC, anyone who employs or contracts with GSC, any hospital or other provider where GSC provides services, and anyone else. This exclusion applies regardless of who submits the claims or other request for payment. GSC shall not submit or cause to be submitted to any Federal health care program any claim or request for payment for items or services, including administrative and management services, furnished, ordered, or prescribed by GSC during the exclusion. Violation of the conditions of the exclusion may result in criminal prosecution, the imposition of civil monetary penalties and assessments, and an additional period of exclusion. GSC further agrees to hold the Federal health care programs, and all federal beneficiaries, parents, sponsors, legally responsible beneficiaries, or third party payors, harmless from any financial responsibility for items or services furnished, ordered, or prescribed to such beneficiaries or sponsors after the effective date of the exclusion. GSC waives any further notice of the exclusion and agrees not to contest such exclusion either administratively or in any state or federal court. This exclusion shall commence upon the Effective Date of this Agreement. Gambro waives and shall not assert any defenses Gambro may

11. Gambro waives and shall not assert any defenses Gambro may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a

remedy sought in such criminal prosecution or administrative action. Gambro agrees that this Agreement is not punitive in purpose or effect. Nothing in this Paragraph 11 or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

- 12. Gambro fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Gambro has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.
- 13. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare carrier or intermediary, DME payor, TMA, or any State payer, related to the Covered Conduct; and Gambro shall not resubmit to any Medicare carrier or intermediary, DME payor, TMA, or any State payer any previously denied claims related to the Covered Conduct, and shall not appeal any such denials of claims.
 - 14. Gambro agrees to the following:
 - a. <u>Unallowable Costs Defined:</u> that all costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47, and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg and 1396-1396v, and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Gambro, its present or former officers, directors, employees,

shareholders, and agents in connection with the following shall be "unallowable costs" on government contracts and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP):

- (1) the matters covered by this Agreement and the GSC Plea Agreement;
- (2) the United States' audit(s), civil, and any criminal investigation(s) of the matters covered by this Agreement;
- (3) Gambro's investigation, defense, and corrective actions undertaken in response to the United States' audit(s), civil and criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);
- (4) the negotiation and performance of this Agreement and the GSC Plea Agreement;
- (5) the payment Gambro makes to the United States

 pursuant to this Agreement and any payments that Gambro may make to

 Relator, including costs and attorneys fees; and
- (6) the negotiation of, and obligations undertaken pursuant to the CIA to:
 - (i) Retain an independent review organization to perform annual reviews as described in Section III of the CIA; and
 - ii) prepare and submit reports to the OIG-HHS.

However, nothing in this Paragraph 14.a.(6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to Gambro. (All costs described or set forth in this Paragraph 14.a. are hereafter, "unallowable costs").

- b. <u>Future Treatment of Unallowable Costs:</u> These unallowable costs shall be separately determined and accounted for in nonreimbursable cost centers by Gambro, and Gambro shall not charge such unallowable costs directly or indirectly to any contracts with the United States or any state Medicaid program, or seek payment for such unallowable costs through any cost report, cost statement, information statement, or payment request submitted by Gambro or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.
- Payment: Gambro further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid, VA, and FEHBP fiscal agents, any unallowable costs (as defined in this Paragraph 14) included in payments previously sought from the United States, or any state Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Gambro or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests,

even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. Gambro agrees that the United States, at a minimum, shall be entitled to recoup from Gambro any overpayment plus applicable interest and penalties, if any, as a result of the inclusion of such unallowable costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be said to the United States pursuant to the direction of the Department of Justice.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice, and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Gambro or any of its subsidiaries or affiliates on the effect of inclusion of unallowable costs (as defined in this Paragraph 14) on Gambro or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

- d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Gambro's books and records to determine that no unallowable costs have been claimed in accordance with the provisions of this Paragraph 14.
- States' investigation and prosecution of individuals and entities, except those for which prosecution has been declined in the Plea Agreement between GSC and the United States. Upon reasonable notice, Gambro shall use its best efforts to encourage, and agrees not to impair, the cooperation of its current and former directors, officers, and employees, consistent with the rights and privileges of such individuals. Gambro shall

furnish to the United States, upon reasonable request, copies of non-privileged documents and records in its possession, custody, and control relating to the Covered Conduct. The United States will not consider Gambro to be in breach of this Paragraph 15 if: (a) Gambro honors non-discretionary obligations imposed on Gambro by applicable law, its bylaws, or joint defense agreements entered into before the Effective Date of this Agreement; (b) Gambro advances or pays, pursuant to its bylaws, legal expenses and fees incurred by its current or former directors, officers, or employees related to the Covered Conduct; or (c) Gambro produces to any of its current or former directors, officers, or employees any documents produced to the United States related to the Covered Conduct. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release in this Agreement any claims against any other person or entity, except to the extent provided for in Paragraph 17 below.

- 17. Gambro waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.
- 18. Gambro warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and shall remain solvent following payment of the Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Agreement, they (a) have intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to

Gambro, within the meaning of 11 U.S.C. § 547(c)(1); and (b) conclude that these				
mutual promises, covenants, and obligations do, in fact, constitute such a				
contemporaneous exchange. Further, the Parties warrant that the mutual promises,				
covenants, and obligations set forth herein are intended and do, in fact, represent a				
reasonably equivalent exchange of value that is not intended to hinder, delay, or				
defraud any entity to which Gambro was or became indebted to on or after the date of				
this transfer, within the meaning of 11 U.S.C. § 548(a)(1).				
19. If within 91 days of the Effective Date of this Agreement or of any				

- 19. If within 91 days of the Effective Date of this Agreement or of any payment made hereunder, Gambro commences, or a third party commences, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors, (a) seeking to have any order for relief of Gambro's debts, or seeking to adjudicate Gambro as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for Gambro or for all or any substantial part of Gambro's assets, Gambro agrees as follows:
 - a. Gambro's obligations under this Agreement shall not be avoided pursuant to 11 U.S.C. § 547, and Gambro shall not argue or otherwise take the position in any such case, proceeding, or action that: (i) Gambro's obligations under this Agreement may be avoided under 11 U.S.C. § 547; (ii) Gambro was insolvent at the time this Agreement was entered into, or became insolvent as a result of the payment made to the United States; or (iii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to Gambro.

If Gambro's obligations under this Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Agreement, and bring any civil and/or administrative claim, action, or proceeding against Gambro for the claims that would otherwise be covered by the releases provided in Section III, Paragraphs 3 through 5 above. Gambro agrees that: (i) any such claims, actions, or proceedings brought by the United States (including any proceedings to exclude Gambro from participation in Medicare, Medicaid, or other Federal health care programs) are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceeding described in the first clause of this Paragraph 19, and that Gambro shall not argue or otherwise contend that the United States' claims, actions, or proceedings are subject to an automatic stay; (ii) Gambro shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceeding which are brought by the United States within 120 calendar days of written notification to Gambro that the releases have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on the Effective Date of this Agreement; and (iii) the United States has a valid claim against Gambro in the amount of \$600,000,000.00, and the United States may pursue its claim in the case, action, or proceeding referenced in the first clause of this Paragraph 19, as well as in any other case, action, or proceeding.

- c. Gambro acknowledges that its agreements in this Paragraph19 are provided in exchange for valuable consideration provided in thisAgreement.
- 20. Except as expressly provided to the contrary in this Agreement, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.
- 21. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement shall be the United States District Court for the Eastern District of Missouri, except that disputes arising under the CIA shall be resolved exclusively under the dispute resolution provisions in the CIA.
- 22. This Agreement may not be amended except by written consent of the Parties. The CIA may not be amended except by written consent of Gambro and OIG-HHS.
- 23. On or before the Effective Date of this Agreement, the Relator shall sign and provide to the United States a Joint Stipulation for Dismissal of the Civil Action ("Joint Stipulation"). Then, within 4 business days after the Effective Date of this Agreement, the United States shall sign and file the Joint Stipulation. The Joint Stipulation shall dismiss with prejudice as to both the United States and the Relator Count I (Method II Supplies), Count III (Method II Emergency Supplies), Count IX (Preemptive Coding), and Count X (Medical Directors), and shall dismiss without prejudice as to the United States and with prejudice as to the Relator Count II (Method II Antibiotics), Count IV (Split Vial Dosing), Count V (EPO Overfill), Count VI (EPO

Rebates), Count VII (Vitamin D Selection), Count VIII (Iron Selection), Count XI (Jackson Memorial Hospital), and Count XII (GNS) of the last-filed complaint in the Civil Action.

- 24. The individuals signing this Agreement on behalf of Gambro represent and warrant that they are authorized by Gambro to execute this Agreement. The individual(s) signing this Agreement on behalf of the Relator represent and warrant that they are authorized by Relator to execute this Agreement. The United States signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.
- 25. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same agreement.
- 26. The Effective Date of the Agreement shall be on the date of signature of the last signatory to the Agreement. The United States shall provide Gambro no less than 3 business days notice in advance of the date of signature of the last signatory to the Agreement.
- 27. This Agreement is binding on the Parties' successors, transferees, heirs, and assigns.
- 28. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.
- 29. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA - Plaintiff

DATED: 12/1/04

JOHN K. HENEBERY
Trial Attorney, Commercial Litigation Branch
Civil Division
United States Department of Justice

THE UNITED STATES OF AMERICA - Plaintiff

DATED: December 2 2004 BY: Claud M. ARA

JAMES G. MARTIN United States Attorney CLAIRE M. SCHENK Assistant United States Attorney
U.S. Attorney's Office for the
Eastern District of Missouri

THE UNITED STATES OF AMERICA - Plaintiff

LEWIS MORRIS
Chief Counsel to the Inspector General
Office of Inspector General
United States Dept. of Health and Human Services

THE UNITED STATES OF AMERICA – Plaintiff

DATED: 30 NOU 2004

LAUREL GILLESPIE
Deputy General Counsel
TRICARE Management Activity
United States Department of Defense

GAMBRO HEALTHCARE, INC. - Defendant

DATED: December 1,2004

Senior Vice President and General Counsel Gambro Healthcare Inc.

GAMBRO HEALTHCARE, INC. - Defendant

THOMAS A CARLUCCI
Foley & Lardner LLP
Counsel to Gambro Healthcare, Inc.

STEVEN J. BANDER, M.D. - Relator

JOHN GIANOULAKIS Kohn, Shands, Elbert, Gianoulakis & Giljum, LLP Counsel for Steven J. Bander, M.D.